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37, and 54 being independent claims. No new matter has been added. Applicants respectfully request reconsideration in view of the foregoing amendments and the following remarks.

Applicants wish to thank the Examiner for the courtesies extended in contacting their undersigned attorney and conducting a telephone interview on November 15, 2002. The substance of the telephone interview is summarized below.

Rejections Under 35 U.S.C. §102

Claims 1-4, 14-17, 20, 21, 37-39 and 42-44

Claims 1-4, 14-17, 20, 21, 37-39 and 42-44 are rejected under 35 U.S.C. §102(b) as being anticipated by Eldridge. (WO 98/49967).

Eldridge discloses an implantable device for repairing tissue or muscle defects comprising a layer of repair fabric including first and second tissue infiltratable sheets and a barrier layer. The Examiner asserts that Eldridge also teaches a peripheral barrier formed by melting the inner sheet of repair fabric to the barrier layer. The Examiner contends that by melting a portion of the middle sheet of repair fabric, "a portion of the outer peripheral edge has been altered to render this edge adhesion resistant."

Applicants have amended independent claim 1 to clearly distinguish over Eldridge. As amended, claim 1 is directed to an implantable prosthesis including, *inter alia*, a layer of repair fabric including a first surface and an outer peripheral edge with a thickness, and a peripheral barrier that extends across the entire thickness and about at least a portion of the outer peripheral edge to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs.

As discussed during the telephone interview, Eldridge does not teach a peripheral barrier that extends across the entire thickness of the outer peripheral edge of the repair fabric as recited in claim 1. Rather, Eldridge discloses a composite prosthesis in which a surface portion of the inner sheet is melted to mechanically fix the barrier layer without affecting the physical characteristics of the outer tissue infiltratable sheet. Accordingly, claim 1 patentably distinguishes over Eldridge et al., such that the rejection under §102 should be withdrawn.

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Claims 2-4, 14-17, 20 and 21 depend from independent claim 1 and are patentable for at least the same reason.

During the telephone interview, the Examiner suggested that Gianturco (U.S. Patent No. 5,258,000) may disclose a prosthesis in which the entire thickness of the peripheral edge is adhesion resistant. As discussed below in connection with the rejection of claim 54, Applicants respectfully disagree.

Independent claim 37 has been amended to clearly distinguish over Eldridge. As amended, claim 37 is directed to an implantable prosthesis including, *inter alia*, a layer of repair fabric including a first surface and an outer margin with an outer peripheral edge, the outer peripheral edge having a thickness, the outer margin having been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs.

Eldridge does not teach an outer margin that has been melted and resolidified to render the entire thickness of the outer peripheral edge of the repair fabric resistant to the formation of adhesions with tissue and organs. Rather, as discussed above, only a surface portion of the inner, second sheet adjacent the barrier layer is melted to fuse the barrier layer to the second sheet. Accordingly, claim 37 patentably distinguishes over Eldridge, such that the rejection under §102 should be withdrawn.

Claims 38, 39 and 42-44 depend from independent claim 37 and are patentable for at least the same reason.

As discussed below, Gianturco fails to disclose an outer margin with its entire thickness rendered adhesion resistant.

Claims 54-59

Claims 54-59 are rejected under 35 U.S.C. §102(e) as being anticipated by Gianturco (U.S. Patent No. 5,258,000).

The Examiner asserts that Gianturco teaches a tissue repair prosthesis comprising a layer of repair fabric (13), a barrier layer (16), and a plurality of stitches (17) joining the barrier and repair fabric layers to create a bite region for added strength and support. The

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Examiner also contends that Gianturco discloses that the barrier layer and repair fabric layer "are heat sealed which inherently involves some degree of melting and re-solidifying to render at least a portion of the outer peripheral edge substantially impervious to tissue ingrowth".

Applicants have amended independent claim 54 to clearly distinguish Gianturco. Claim 54 is directed to an implantable prosthesis comprising, *inter alia*, a layer of repair fabric including an outer margin with an outer peripheral edge adapted to inhibit the formation of adhesions thereto. As amended, the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

Gianturco indicates that first and second sheets 13, 16 of material are attached about the circumference 15 of the foldable (first) sheet using a well-known heat seal process. While this may involve some degree of melting and resolidifying of one or both layers, it does not follow that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto as recited in claim 54. Rather, the degree of melt would vary depending on a number of factors including die design, applied pressure, dwell time, temperature (heated die process) and frequency (sonic weld process). Thus, one of ordinary skill in the art would recognize that attaching layers of material using a heat seal process does not necessarily result in the entire thickness of the outer peripheral edge being adapted to inhibit adhesion formation. Accordingly, claim 54 patentably distinguishes over Gianturco, such that the rejection under §102 should be withdrawn.

Claims 55-59 depend directly and indirectly from independent claim 54 and are patentable for at least the same reason.

Rejections Under 35 U.S.C. §103

Claims 18, 19, 45-48 and 53

Claims 18, 19, 45-48 and 53 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eldridge et al. in view of Sharber. (U.S. Patent No. 6,075,180).

Without acceding to the propriety of these rejections, claims 46-48 and 53 have been canceled, and claims 18-19 and claim 45 depend from independent claims 1 and 37, respectively, and are patentable for at least the same reasons set forth above.

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Claims 49-52 and 54-59

Claims 49-52 and 54-59 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eldridge in view of Sharber and in further view of Darois. (U.S. Patent No. 6,258,124).

Without acceding to the propriety of these rejections, claims 49-52 have been canceled.

Independent claim 54 has been amended, as discussed above, to distinguish over Gianturco. As amended, claim 54 recites that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto. As discussed above in connection with independent claims 1 and 37, Eldridge does not teach a layer of repair fabric in which the entire thickness of the outer peripheral edge is adhesion resistant. Neither Sharber nor Darois cures this deficiency. Accordingly, amended claim 54 is patentable over the combination of Eldridge, Sharber and Darois, such that the rejection under §103 should be withdrawn.

Claims 55-59 depend from independent claim 54 and are patentable for at least the same reason.

Claims 5-7, 29-36 and 40-41

Claims 5-7, 29-36 and 40-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eldridge in further view of Pajotin. (U.S. Patent No. 6,368,541).

Without acceding to the propriety of these rejections, claims 5-7 and claims 40-41 depend from independent claims 1 and 37, respectively, and are patentable for at least the same reasons set forth above.

Independent claim 29 is directed to an implantable prosthesis for repairing a tissue or muscle wall defect. The prosthesis comprises, *inter alia*, a layer of repair fabric including an inner body and outer margin extending from the inner body, wherein the outer margin includes an outer peripheral edge that has a thickness that is less than the thickness of the inner body.

Eldridge does not disclose a layer of repair fabric having an outer peripheral edge with a thickness that is less than the thickness of the inner body of the repair fabric as recited in claim 29. In the Office Action, the Examiner contends that Pajotin teaches an implantable prosthesis that has a tapered peripheral edge to assist implantation. The Examiner concluded

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that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Eldridge prosthesis to include a tapered edge in view of Pajotin to assist implantation of the prosthesis into the body. Applicants respectfully disagree for at least the same reasons set forth in their prior response dated August 16, 2002, which is incorporated herein by reference.

Notwithstanding the lack of motivation alleged by the Examiner, Applicants have amended claim 29 to further distinguish over the references. As amended, claim 29 recites that the entire thickness of the outer peripheral edge is adapted to inhibit the formation of adhesions thereto.

As discussed above, Eldridge does not teach or suggest a prosthesis that includes a layer of repair fabric having an outer peripheral edge with its entire thickness adapted to inhibit the formation of adhesions thereto. Although Pajotin teaches fusing the margins of a curved prosthesis, one of ordinary skill in the art would have been directed away from modifying the entire thickness of the outer peripheral edge of Eldridge in this manner. Eldridge employs an inner mesh sheet that is fused to the barrier layer so as to allow the outer mesh sheet to retain its full tissue ingrowth potential and strength. (See Eldridge, page 2, lines 5-8 and 18-19, page 5, lines 3-7, and page 6, lines 7-13). Eldridge clearly teaches avoiding any physical changes to the outer sheet of mesh. Thus, one of ordinary skill in the art would *not* have been motivated to fuse the outer margin of the Eldridge prosthesis in a manner that would result in the entire thickness of the outer peripheral edge being adapted to inhibit the formation of adhesions thereto.

In view of the foregoing, claim 29 patentably distinguishes over Eldridge and Pajotin, such that the rejection under §103 should be withdrawn. Claims 30-36 depend from independent claim 29 and are patentable for at least the same reasons.

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CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Cherok et al., Applicants

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MARKED-UP CLAIMS

1. (Amended) An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface and an outer peripheral edge with a thickness;

a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs; and

a peripheral barrier that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending across the entire thickness of the outer peripheral edge and about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs.

29. (Amended) An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including an inner body with a first surface and an outer margin extending from the inner body, the outer margin including an outer peripheral edge, each of the inner body and the outer peripheral edge having a thickness, the thickness of the outer peripheral edge being less than the thickness of the inner body, the entire thickness of the outer peripheral edge adapted to inhibit the formation of adhesions thereto; and

a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs.

37. (Amended) An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

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a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface and an outer margin with an outer peripheral edge, the outer peripheral edge having a thickness, the outer margin having been melted and resolidified to render the entire thickness of the outer peripheral edge resistant to the formation of adhesions with tissue and organs; and

a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs.

54. (Twice Amended) An implantable prosthesis for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

a layer of repair fabric that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including an outer margin with an outer peripheral edge having a thickness, the entire thickness of the outer peripheral edge being adapted to inhibit the formation of adhesions thereto, the outer margin being reinforced to form a bite region that is spaced inward of the outer peripheral edge for securing the prosthesis along the outer margin; and

a barrier layer that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the layer of repair fabric and adjacent tissue and organs.

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